IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Daniel FLAMMANG

Appl. No. 09/586,942

Confirmation No.: 6577

Filed: June 2, 2000

For: ELECTRODE LEAD WITH MULTIPLE BRANCHES (as amended)

Art Unit: 3762

Examiner: F. OROPEZA

Atty. Docket No. 31512-172579

Customer No.

26694

PATENT TRADEMARK OFFICE

Assistant Commissioner for Patents
Washington, D.C. 20231

APPEAL BRIEF

Sir:

This is an Appeal to the Board of Patent Appeals and Interferences from the decision in the Office Action mailed May 22, 2002. An Amendment After Final Rejection was filed on August 12, 2002 and having received an Advisory Action dated August 22, 2002, Appellant timely filed a Notice of Appeal and Request for an Extension of Time on September 27, 2002. Appellant now presents herewith this Appeal Brief in triplicate pursuant to 37 C.F.R. § 1.192.

(1) REAL PARTY IN INTEREST

The Assignee of this Application, and thus the real party of interest in this Appeal is Daniel Flammang by virtue of the initial assignee, BIOTRONIK Meß-und Therapiegeräte GmbH & Co. Ingenieurbüro Berlin, having a business address at Woermannkehre 1, D-12359 Berlin, Germany, assigning the rights of the patent application back to the inventor on July 18, 2001.

(2) RELATED APPEAL AND INTEREFERENCES

No Appeal or Intefererences is known to Appellant, the Appellant's legal representative or Assignee which would directly affect or be directly affected by or have a bearing on the Board's decision in the pending Appeal.

(3) STATUS OF CLAIMS

The Application was filed with claims 1-12, which were canceled and replaced with new claims 13-25 in the Amendment filed February 28, 2002. Claim 13 was cancelled and replaced with amended claim 20 written in independent claim form and claims 14-17 and 19 were amended in the Amendment After Final Rejection filed April 12, 2002. The April 12, 2002 Amendment was indicated as being entered in the corrected Advisory Action that was issued August 27, 2002. No explanation of the how the amended claims would be rejected was provided; however, it appears that the Examiner maintained her rejection of claim 20 as set forth in paragraph 6 of the May 22, 2002 final Office Action.

Accordingly, claims 20 and 14-19 and 21-25 are rejected.

Claims 20, 14-19 and 21-25 are appealed and set forth in the Appendix to this Brief.

(4) STATUS OF AMENDMENTS

The Amendment After Final Rejection filed on August 12, 2002 was entered for the purposes of Appeal and the corrected Advisory Action indicated that the amended claims overcame the rejection under 35 U.S.C. § 112, second paragraph.

(5) SUMMARY OF THE INVENTION

The invention is directed to an electrode arrangement for endocardial discharge of defibrillation pulses in the atrium or a ventricle of the heart (page 1, lines (after the title) 1-2 of the instant specification). As shown in Figures 1a-1d, the electrode lead (10) has an undivided promixal end (at the top of the Figures), a distal end and a splitter from which at least two branches (14, 16) of the electrode lead extend to the distal end. The central core of each branch (14,16) extends from the splitter to the distal end and is made of a memory metal structure to enable good contact to be maintained between each branch (14,16) and a wall of the atrium or the ventricle (page 4, line 24 through page 5, line 9 and shown in Figure 7 of the instant specification). A plurality of electrically conductive surface portions (32 and 30) are disposed on the at least two branches (14,16) where the plurality of electrically conductive surface portions are electrically connected by way of the electrode lead (10) to an electrical pulse-discharging device (not shown) at the proximal end of the electrode lead (10) (Page 8, lines 4-15 of the instant specification). The at least two branches include a septal branch (14) and a lateral branch (16), which each have an equal number of electrically conductive surface portions disposed thereon and each electrically conductive surface portion (32 and 30) of the septal branch (14) is unambiguously associated with an electrically conductive surface portion on the lateral branch (16). The dash-dotted lines of Figure 2b joining electrodes (30 and 32) of the septal branch (14) to unambiguously associated electrodes (30 and 32) of the lateral branch clearly illustrate the layers defined in the atrium by the associated electrode pairs. See page 5, lines 10-16 and page 9, lines 17-27 of the originally-filed Specification.

As a result of this claimed structure, it is possible for electrodes to be positioned on mutually, oppositely disposed sidewalls of the heart and for the electrodes to be actuated, for

example, in bipolar mode so that unambiguously associated electrodes (in pairs) can serve as an anode and a cathode for the discharge of voltage pulses to the myocardium (cardiac tissue) of the atrium. See the paragraph spanning pages 3 and 4 of the instant specification. That is, the electrode lead according to the invention can assume positions in the heart so that associated electrodes in the septal and lateral branches define layers starting from the transition of the vena cava of the heart into the atrium thereof, thereby subdividing the atrium of the heart in parallel successive relationship (page 5, line 26 through page 6 of line 3 of the instant specification). Further, the inventive electrode arrangement makes it possible for the atrium to be stimulated in layers either successively in time-displaced relationship in a cascade-like procedure or simultaneously with bipolar voltage pulses in order to increase the accuracy of the diagnosis of arrhythmia, especially the fibrillation of atria and vertricles. Therefore, the claimed invention can achieve a defibrillation effect with an extremely low level of stimulation energy and provide defibrillation which can be substantially pain-free for the patient (page 6, lines 9-15 of the instant specification).

(6) ISSUES

The issues on appeal are as follows:

I Whether claims 14, 16 and 19-24 are properly rejected under 35 U.S.C. § 103(a) as being unpatentable over McGee et al. (U.S. Patent No. 5,855,592, hereinafter referred to as "McGee") in view of European Patent Application No. 0 601 328 to Ljungström (hereinafter referred to as "Ljunström")?

II. Whether claims 15, 17 and 18 were properly rejected under 35 U.S.C. § 103(a) as being unpatentable over McGee in view of Ljungstöm and further in view of Cookston et. al. (U.S. Patent No. 5,834,031, hereinafter referred to as "Cookston")?

III. Whether claim 25 was properly rejected under 35 U.S.C. § 103(a) as being unpatentable over McGee in view of Ljungstöm and further in view of Hess et. al. (U.S. Patent No. 4,664,120)?

(7) GROUPING OF CLAIMS

An independent defense is presented in connection with independent claim 20. However, no independent defense is presented with respect to depending claims 14-19 and 21-25. Accordingly, the dependent claims stand or fall together with the independent claim.

(8) ARGUMENT

I. CLAIMS 14, 16 AND 19-24 ARE PATENTABLE OVER McGEE IN VIEW OF LJUNGSTRÖM UNDER 35 U.S.C. § 103(a)

Appellant will show that the combination of McGee in view Ljungström does not render obvious the subject matter of independent claim 20 under 35 U.S.C. § 103(a).

I. A. The Examiner's Position

The Examiner's Action states on the Continuation Sheet attached to the Advisory Action mailed August 22, 2002 that

> Mc Gee et al. teach the number of splines and electrodes can vary depending on the application (c 6, ll 32-36). Ljungström teaches in figure 4 the use of two branches to provide stimulation therapy. Since Mc Gee et al. focuses the

stumulation [sic] therapy about the interatrial septium (c 3, ll 9-12), the two branches are read as the septal branch and the lateral branch.

The Examiner finds that Mc Gee et al. provide a system and method for assessing organization of the heart rhythm in the heart tissue and provides organization - indicating output which is characterized by a geometric form (c 2, ll 51-64). Pacing pulses with selected pulse characteristics are delivered through an array of an electrodes to entrain regions of the heart (c 3, ll 3-20). The pacing is varied as need to address the cardiac condition, the physiological constraints and the spacing between electrodes (c 4, ll 13-21; c 8, ll 15-28; c 9, ll 38-55). ...In one embodiment the algorithm delivers the first set of pacing pulse to the band of most distal electrodes on each spline element, then proceeds in sequence to adjacent bands of electrodes in succession towards the most proximal band of electrodes on each spline element (c 9, l 60-c 10, l 6); this is read as "each electrically conducted surface portion (the electrode) of the septal branch is unambiguously associated with an electrically conductive surface portion (the electrode) of the lateral branch". See lines 13-31 of the Continuation Sheet.

Thus, it is the Examiner's position that the disclosure in column 9, line 60 though column 10, line 6 of McGee teaches more than electrodes of one branch being pulsed in succession and electrodes of another branch being pulsed in succession.

B. The Appellant's Position

As the Examiner's comment on the Continuation Sheet recognizes, column 4, lines 16-19 of McGee actually teach against an association of electrodes on different branches. In particular, McGee discloses:

> Alternatively, one or both atria can be entrained by pacing electrodes located over a large area using the same pacing rate at all electrodes, but applying pacing signals from different electrodes at different times. (Emphasis provided, column 4, lines 16-19 of McGee).

While it is true that McGee states that an algorithm 54 delivers a first set of pacing pulses to the band of the most distal electrodes on each spline and then proceeds in sequence to adjacent bands of electrodes in succession toward the most proximal band of elements on the spline elements, nowhere does McGee positively override the earlier statement that pacing signals from

different electrodes are applied at different times. Nowhere does McGee state the electrodes of one branch are unambiguously associated with electrodes of another branch.

Contrary to the layers, defined by the unambiguously associated electrodes (or electrodes in pairs) of claim 20, as shown in Figure 2b, McGee describes an algorithm that expands the targeted atrial region beyond the local atrial region to entrain a successively larger area about the localized area (see column 3, lines 30-33 of McGee). That is, McGee teaches that a single electrode only stimulizes a localized area whereas a spaced apart array of electrodes can monitor electrically events at spaced apart areas in the heart tissue region. Nowhere does McGee disclose, teach or even suggest that the electrodes of one branch are to be unambiguously associated with (or paired with) electrodes of another branch to define layers of a heart, which is the result of Appellant's electrically conductive surface portion of a septal branch being unambiguously associated with an electrically conductive surface portion of a lateral branch as recited in independent claim 20.

It is respectfully submitted that McGee, at most, teaches that a plurality of spaced apart electrodes will stimulate a larger area of a heart. This is not Appellant's invention.

The secondary reference to Ljungström is applied for its teaching of two branches of a defibrillation system. While it is the Examiner position is that Ljungström teaches a lead configuration that contains a septal branch and a lateral branch with a distal tip electrode to optimize the defibrillation system, nowhere does the Action or Continuation Sheet identify disclosure in Ljungström that states that each electrode of the septal branch is unambiguously associated with an electrode of the lateral branch. As stated above and claimed, this is Appellant's invention. It is this unambiguous association or pairing of electrodes disposed on

different branches that enables the inventive electrode arrangement to achieve a defibrillation effect with an extremely low level of stimulation energy thereby providing a substantially pain-free defibrillation treatment. Nowhere does McGee or Ljungström recognize the advantage of unambiguously associating electrodes on different branches. Thus, both McGee and Ljungström, taking alone or in combination fail to teach the claimed invention.

Ljungström teaches an electrode arrangement similar to that of McGee where a plurality of spaced-apart electrodes are mounted on individual branches. The mere fact that an electrode arrangement has a plurality of branches with a plurality of electrodes disposed on each branch does not amount to a disclosure that each electrode of one branch are unambiguously associated with an electrode of the other branch. It is this unambiguous association that enables each electrically conductive surface portion of a septal branch and corresponding electrically conductive surface portion of a lateral branch to subdivide the atrium into a corresponding number of identical slices as shown in Fig. 2b. As a result, a timely and effective defibrillation with a current weaker than previously thought possible is provided and results in a procedure with a lower pain level for the patient. Neither McGee nor Ljungström disclose, teach or suggest such an electrode arrangement. Nor do they disclose, teach or suggest a reason to associate electrodes of one branch with electrodes of another branch to achieve a defibrillation procedure involving a lower pain level for the patient. Accordingly, it is respectfully submitted that there is no motivation to modify the algorithm that pulses electrodes along a branch to stimulate a larger area of the heart to be unambiguously associated with electrodes of another branch so that the two associated electrodes define slices of an atrium thereby allowing defibrillation with weaker currents than previously thought possible. As neither McGee or Ljungström consider the amount of pain associated with current defibrillation procedures a problem, it is respectfully submitted

that one of ordinary skill in the art would not have thought to modify the algorithm of McGee based on the teachings of Mcgee or Ljungström that oppose the association of electrodes of different branches, as claimed by Appellants.

As stated by the Federal Circuit in Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 796 F.2d 443, 230 USPQ 416 (1986), "a single line in a prior art reference should not be taken out of context and relied upon with the benefit of hindsight to show obviousness." The numerous sections of McGee cited on the Continuation Sheet attached to the Advisory Action mailed August 22, 2002 are concerned with stimulating a larger area about a localized area and not with defining slices of the heart, as Appellant's claimed invention achieves as a result of its unambiguously associated electrically conductive surface portions. It is respectfully submitted that the general teachings of McGee and Ljungström referenced in the Advisory Action fail to overcome the fact that those references lack the claimed unambiguous association of electrodes of a septal branch with a respected electrode of a lateral branch. That is, the general teachings of McGee and Ljungström do not by themselves teach Appellant's claimed invention and is respectfully submitted that the Examiner is falling into the hindsight syndrome by using the Appellant's disclosure to improperly modify McGee.

At the time of Appellant's invention, one possible way to pace or defibrillation was to use one electrode (unipolar) or two electrodes on the same lead (bipolar). Currently, this is still the method employed in systems available for intracardia defibrillation. Nowhere does McGee provide a hint that dividing of cardiac tissues may result in a better defibrillation device. It is the dividing of the cardiac tissue, which occurs as a result of the recited electrically conductive surface portions of the septal branch being unambiguously associated with an electrically conductive surface portion of the lateral branch that enable a defibrillation procedure to employ a

lower current level than previously thought possible. In as much as the known prior art, as well as explicit teachings from McGee, teach applying pulsing signals from different electrodes at different times, it is respectfully submitted that one of ordinary skill in the art would not have considered reconstructing the algorithm taught by McGee to that of the claimed invention.

It is respectfully submitted that the Examiner employed impermissible hindsight reconstruction of the general disclosures of McGee and Ljungström to achieve Appellant's invention. Clearly, neither reference discusses nor suggests unambiguously associating an electrode of a septal branch with an electrode of a lateral branch. Thus, it is only the Appellant's own disclosure that recognizes the importance of unambiguously associating electrodes of a septal branch with electrodes of a lateral branch to provide effective defibrillation with a lower current, which is less painful for the patient.

II. CLAIMS 15, 17 AND 18 ARE PATENTABLE OVER McGEE IN VIEW OF LJUNGSTRÖM AND FURTHER IN VIEW OF COOKSTON UNDER 35 U.S.C. § 103(a)

Cookston is directed to an apparatus and method for deflecting a tip of a lead or catheter. Nowhere does Cookston address, let alone, disclose, teach or suggest an electrode lead having at least two branches including a septal and a lateral branch where electrically conductive surface portions disposed on a respective branch are unambiguously associated with an electrically conductive surface portion of the other branch. Accordingly, Cookston does not provide the teaching missing from the above combination as argued above and cannot render the claimed invention obvious.

III. CLAIM 25 IS PATENTABLE OVER McGEE IN VIEW OF LJUNGSTRÖM AND FURTHER IN VIEW OF HESS UNDER 35 U.S.C. § 103(a)

The Action applied Hess for its teaching of a lead configuration that contains two atrial electrode branches 16 and a ventricular branch 15 to provide a multi-functional lead. Nowhere does Hess disclose at least two branches including a septal branch and lateral branch. Moreover, Hess also fails to disclose, teach or suggest the unambiguously associated electrically conductive surface portions of any two branches, let alone the claimed septal and lateral branches. Accordingly, Hess does not provide the teaching missing from the above combination and cannot render the claimed invention unpatentable.

(9) CONCLUSION

For the foregoing reasons, it is respectfully submitted that independent claim 20 and its dependent claims 14-19 and 21-25 are patentable over McGee in view of Ljungström, either alone or in combination with any of the prior art of record. Accordingly, the Examiner's rejection of these claims should be reversed.

The $320.00 fee set forth in 37 C.F.R. § 1.17(c) is submitted herewith. Should the remittance be missing or should any additional fees be required, the Commissioner may charge

the appropriate amount to our Deposit Account No. 22-0261.

Date: November 25, 2002

Respectfully submitted,

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APPENDIX

Pending claims 20, 14-17, 19 and 21-25 are as follows:

20. An electrode arrangement for the endocardial discharge of defibrillation pulses in one of the atrium and ventricle of the heart, comprising:

an electrode lead having an undivided proximal end, a distal end and a splitter from which at least two branches of the electrode lead extend to the distal end, each branch having a central core extending from the splitter of the electrode lead, said central core being made of a memory member structure that enables good contact to be maintained between each branch and a wall of the atrium or the ventricle; and

a plurality of electrically conductive surface portions disposed on the at least two branches, said plurality of electrically conductive surface portions being electrically connected by way of the electrode lead to an electrical pulse-discharging device at the proximal end of the electrode lead, wherein the at least two branches include a septal branch and a lateral branch, and the septal branch and lateral branch each have an equal number of electrically conductive surface portions disposed thereon, and each electrically conductive surface portion of the septal branch is unambiguously associated with an electrically conductive surface portion of the lateral branch.

14. The electrode arrangement according to claim 20, further comprising a sliding sleeve displaceable in a longitudinal direction of the electrode lead and actuating means for actuating the sliding sleeve wherein said central core is of one-piece construction in the form of a spring element and causes the branches to split apart when the actuating means moves the sliding sleeve toward the proximal end of the electrode lead.

15. The electrode arrangement according to claim 20, further comprising a sliding sleeve displaceable in a longitudinal direction of the electrode lead, means for actuating the sliding sleeve to split the at least two branches apart, and means for heating the memory member structure so that the shape of the memory member structure can change to maintain good contact between each branch and a wall of the atrium or the ventricle.

16. The electrode arrangement according to claim 15, wherein the memory member structure in at least one of the at least two branches is activatable simultaneously or after the actuating of the sliding sleeve, and a first branch assumes a shape as the septal branch and a second branch assumes a shape as the lateral branch for respectively assuming a septal position and a lateral position in one of the atrium and the ventricle of the heart.

17. The electrode arrangement according to claim 15, wherein at least one memory member structure, in at least one of the branches, experiences a predetermined change in shape by being heated above a predetermined temperature.

18. The electrode arrangement according to claim 17, wherein the memory member structure contains titanium.

19. The electrode arrangement according to claim 20, wherein the electrode lead is split into three different branches.

21. The electrode arrangement according to claim 20, wherein the septal and lateral branch each has disposed thereon about 5 to 7 electrically conductive surface portions.

22. The electrode arrangement according to claim 20, wherein the electrically conductive surface portions are in the form of ring electrodes.

23. The electrode arrangement according to claim 21, wherein at least one of the ring electrodes are formed at the tip or distal end of at least one of the at least two branches.

24. The electrode arrangement according to claim 19, wherein the electrically conductive surface portions of each branch are respectively spaced approximately one centimeter from adjacent electrically conductive surface portions.

25. The electrode arrangement according to claim 19, wherein the at least two branches further includes a ventricular branch which is adapted to assume a position in a ventricle of the heart and has at least one ventricle electrode.